UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

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IN RE BIOVIE INC. SECURITIES LITIGATION

Case No. 3:24-cv-00035-MMD-CSD

ORDER

I. SUMMARY

Plaintiffs[1] representing a putative class of investors bring this securities fraud action against Defendant BioVie, Inc. ("BioVie," or "the Company"), a clinical-stage biopharmaceutical company, and two of its senior executives[2]. (ECF No. 37 ("Amended Complaint").) Plaintiffs allege that BioVie and its leaders concealed widespread patient fraud during a pivotal Phase 3 clinical trial designed to evaluate the safety and efficacy of the Company's lead drug candidate as a treatment for Alzheimer's Disease. (*Id.*) The clinical trial ultimately failed to reach statistical significance after data from over 80% of enrolled patients was excluded from analysis, following revelation of improper conduct at 15 clinical trial sites. Plaintiffs assert that they purchased and owned BioVie securities at an artificially inflated price, bringing claims under Sections 10(b) and 20(a) of the Securities Exchange Act, 15 U.S.C. §§ 78j(b), 78t(a), and Securities and Exchange Commission ("SEC") Rule 10b-5(b), 17 C.F.R. § 240.10b-5. (*Id.*)

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[1]Lead plaintiff is Dr. Anthony Rinaldi; Mark Hill is an additional named plaintiff. (ECF No. 37 at 1.)

[2]Senior executives named as defendants are BioVie's President and Chief Executive Officer, Cuong Do, and Chief Medical Officer Joseph Palumbo. (*Id.*)

Before the Court are Defendants' motion to dismiss the Amended Complaint (ECF No. 38 ("Motion")[3]) and related request for judicial notice (ECF No. 43). Because Plaintiffs adequately allege the elements of a Section 10(b) claim under the heightened pleading standards applied in securities fraud cases, the Court will deny the Motion and allow this action to proceed within the limitations set out below.

II. BACKGROUND[4]

BioVie is a biopharmaceutical company developing drug therapies for the treatment of neurological and neurodegenerative disorders. (ECF No. 37 at 7-8.) Senior executives named as defendants in this action are BioVie's President and CEO, Cuong Do, and Executive Vice President and Chief Medical Officer Joseph Palumbo ("Individual Defendants"). (*Id.* at 4-5.)

A. Initiation of Phase 3 Clinical Trial

BioVie acquired its lead drug candidate, Bezisterim (also referred to as "NE3107") from an affiliated biopharmaceutical company in June 2021. (*Id.* at 8-9.) Since acquiring NE3107, BioVie has touted the drug's potential to spur "an entirely new medical approach" to treating both Alzheimer's Disease and Parkinson's Disease through its novel anti-inflammatory and insulin-sensitizing mechanisms targeting neurodegeneration. (*Id.* at 8.) NE3107 featured prominently in investment analyst commentary on BioVie's prospects after the Company's acquisition, with Cantor Fitzgerald describing NE3107 as a "potential blockbuster opportunity" when it initiated coverage in July 2022. (*Id.* at 8-9.) In August 2022, BioVie entered into a stock sales agreement with Cantor Fitzgerald and B. Riley Securities. (*Id.* at 12.)

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[3]Plaintiffs responded (ECF No. 44) and Defendants replied (ECF No. 46).

[4]The following facts are adapted from the Amended Complaint or, where appropriate, documents incorporated into the Amended Complaint by reference or properly subject to judicial notice. Where portions of documents quoted in the Amended Complaint are also attached as exhibits to Defendants' request for judicial notice, the Court cites to the docket locations interchangeably.

On August 5, 2021, BioVie initiated a Phase 3 clinical trial ("the Study'), also referred to as "NM101," to evaluate the effectiveness of NE3107 in subjects with mild to moderate Alzheimer's Disease. (*Id.*) A Phase 3 clinical trial generally tests safety and efficacy factors in an expanded patient population after Phase 1 and 2 investigational studies, often comparing a drug with placebos to "establish the overall risk-benefit profile of the product." (*Id.* at 7.) NM101 was a potentially "pivotal" clinical trial—a term of art under Federal Drug Administration ("FDA") procedures—because BioVie expected to rely on the results to demonstrate NE3107's safety and efficacy in a New Drug Application ("NDA") seeking FDA marketing approval. (*Id.* at 8.) The Study was designed as a randomized, double-blind, placebo-controlled protocol. (*Id.*) The initial enrollment target was roughly 316 patients. (*Id.* at 19-20.)

As a sponsor organization, BioVie contracted with a third-party contract research organization ("CRO") to manage and monitor compliance at the clinical sites collecting data. (*Id.* at 8, 23, 34.) As BioVie has represented, each clinical site was responsible for uploading its blinded data to an electronic database ("EDC") maintained by BioVie's CRO, the Cognitive Research Corporation. (*Id.* at 17.) For most of the Study's data-collection period, BioVie had read-only access to blinded data on the EDC, but was responsible for monitoring the database on an ongoing basis to ensure timely entry. (*Id.*) NM101 was originally set to be completed in late 2022, before BioVie extended the target completion date to mid-2023. (*Id.* at 8.)

By September 2022, approximately 150 patients were enrolled in NM101, and the Study was approaching a review by a data safety monitoring board ("DSMB") scheduled for the end of the calendar year. (*Id.* at 9.) A DSMB is an independent group of experts which provides oversight during clinical trials, including by reviewing study data, protocol, and procedures. (*Id.*) NM101's study protocol provided for interim DSMB review when 50% of patients had completed the Study (ECF No. 40-2 at 29.)

On December 7, 2022, BioVie filed a current report on Form 8-K with the SEC. (ECF No. 37 at 19-21 ("December 7, 2022, Form 8-K").) In an attached letter to

shareholders and investor presentation, BioVie announced that it would forgo the interim DSMB analysis and instead increase enrollment to 400 patients, citing the fact that it had finished enrolling all 316 patients initially targeted before 50% of patients completed the Study. (*Id.*)

B. December 2022 Audit

During the fall of 2022, while BioVie was preparing for DSMB review, concerns began to emerge about "potential misconduct" at one of NM101's principal study sites (Site No. 145) in Cutler Bay, Florida. (*Id.* at 9-10.) By December 2022, Site No. 145 had enrolled 43 patients—roughly 10% of the revised total enrollment target. (*Id.*) By that time, however, the site was under an "enrollment hold," meaning that NM101's principal investigator and/or BioVie had determined that "potential misconduct" necessitated a pause in registration of new patients. (*Id.*)

On December 28 and 29, 2022, BioVie "was forced to undergo" a "'for-cause' audit" at Site No. 145.[5] (*Id.*) An independent firm, Pitts Quality Consulting ("Pitts"), conducted the audit to "assess[] the site's compliance with NM101's study protocol, GCPs . . . applicable regulations, standard operating procedures, and the adequacy of study monitoring occurring at the site." (*Id.*) In the clinical-trial context, a for-cause audit is an investigation into a specific problem that has "come to either the FDA's attention or the attention of the study's investigator or sponsor (*i.e.* BioVie)." (*Id.*)

After completing their review at Site No. 145, Pitts auditors concluded that the site's "level of compliance was unacceptable," and that existing site monitoring was inadequate. (*Id.*) Auditors made a series of critical, major, and minor observations. Most significantly, they found that "the eligibility of subjects in the NM101 study [at the site] could not be confirmed due to lack of data integrity" in patient medical history records, noting data irregularities which indicated potential falsification to render patients eligible

[5]The Amended Complaint does not provide detail as to the specific concerns at Site No. 145 precipitating the Pitts Audit—and how and by whom these concerns were identified, although BioVie states in its Motion that the Pitts Audit occurred at its own request (ECF No. 38 at 11.)

for NM101. (*Id.*) These irregularities included, *inter alia*, inconsistent formatting suggesting inserted text, postdated treatments suggesting that treatment in fact occurred after the date recorded, discrepancies in fax and header dates, and the absence of Alzheimer's Disease diagnosis dates. (*Id.* at 10-12.) Auditors found that six enrolled subjects had received an Alzheimer's Disease diagnosis on the same day, with half of those patients coming from the same medical office, and the diagnoses provided via telemedicine. (*Id.*) In addition, they concluded that "patient testing was not being administered uniformly across patients, due to different individuals rating patient responses using different languages" and lack of translations for non-English speaking patients. (*Id.*) And auditors noted that, although BioVie's contracted CRO was monitoring visits every six to ten weeks, this monitoring was "inadequate given that the above issues were not reported." (*Id.*)

Auditors recommended that BioVie continue the enrollment hold at Site No. 145 and "close the site due to the extent of the noncompliance identified." (*Id.*) The Pitts Audit findings were presented at an audit closing meeting on December 29, 2022, which Site No. 145 Director Jose Marichal and NM101's Principal Investigator Dr. Carlos Martinez attended, along with clinical research coordinators and a research associate from BioVie's CRO. (*Id.*) After the closing meeting, BioVie received the auditor's report for review and acceptance, and "was required to respond in writing regarding corrective actions." (*Id.* at 12.)

C. Continued Data Collection & Initial Blinded Data Review

Plaintiffs allege that after receiving Pitts Audit findings, despite being directed to respond and take corrective measures, BioVie failed to take action at Site No. 145; and problems at the site continued unabated into 2023. (*Id.*)

Meanwhile, BioVie's SEC filings and corporate press releases included information about NM101's progress. On February 10, 2023, BioVie filed a quarterly report announcing that the Company aimed to complete NM101 in the third quarter of 2023 and that the Study was "approaching full enrollment." (*Id.* at 22 ("February 10,

2023, Form 10-Q").) BioVie also told investors that the Company relied on third-party organizations and CROs to conduct the trial, and that if these organizations failed to comply with protocol or good clinical practices, Study results and FDA marketing applications could be delayed. (*Id*.) On March 2, 2023, BioVie issued a press release announcing that it had achieved its 400-patient revised enrollment target, and that it expected top-line results in October 2023. (*Id.* at 25 ("March 2, 2023, Press Release").) And on March 23, 2023, the Company filed a current report on Form 8-K and attached an investor presentation reaffirming NM101's full enrollment and anticipated top-line result timeline. (*Id.* at 26-27 ("March 23, 2023, Form 8-K").)

In its March 23, 2023, Form 8-K, BioVie also stated that "[NM101] continues to have a good safety profile and low discontinuation rate…Blinded baseline data shows evidence of metabolic inflammation in Amyloid [beta] positive and negative, and APOE[]4 positive and negative subjects" specifying these early findings were "submitted for presentation at the American Diabetes Association's 83rd Scientific Sessions." (*Id*.) On May 12, 2023, BioVie filed a quarterly report again indicating that enrollment had been completed and that the Company was now targeting the fourth quarter of 2023 for primary study completion. (*Id.* at 29 ("May 12, 2023, Form 10-Q").)

By the early summer of 2023, NM101 clinical sites began finishing their patient-facing activities, and BioVie began its review of the initial blinded data. (*Id.* at 16.) BioVie "started noticing unusual data patterns when enough patients completed the trial" around this time.[6] (*Id.* at 15-16 (November 29, 2023, Form 8-K).) The Company observed that the preliminary blinded data showed certain deviations from expected

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[6]At least, this is what Defendants told investors months later in November 2023 (after extensive patient data exclusions) when they described BioVie's decisions during the previous summer. Defendant Do would tell investors in November that "[BioVie] took this level of proactive actions [over the summer of 2023] and diligence that goes way above what is typically done by pharma companies because we understood the importance of this data." (*Id.* at 17.) Defendants also represented in November 2023 that, while the Company had become aware over the summer that data from some clinical sites and demographic groups appeared to show anomalies, it was not possible to identify the cause of the anomalies without unblinding data. (*Id.* at 15-17.)

patterns, missing data, and copied-and-pasted MRI results. (*Id.*) As a result of the higher-than-expected level of deviations in initial data, BioVie hired biostatistics firm Pentara to consult on the blinded data. (*Id.* at 17-19 (November 29, 2023, Conference Call).) Pentara's review showed that at several sites, unusual data showed "large proportions of patients improving compared to baseline." (*Id.* at 16.) And notably, data for all patients in a particular demographic group substantially deviated from historical data and expected disease progression. (*Id.*) Around July of 2023, as part of its end-of-study data review, BioVie also began to send clinical research associates to visit sites to "spot check" data entry, including at the sites Pentara had identified. (ECF No. 40-13 at 3 (extended November 29, 2023, conference call transcript).) After these visits revealed further irregularities, BioVie engaged two supplemental CROs, including GeoSera, Inc., for a "multi-step review" which would involve quality control visits and source data verification at all of the Study's 39 clinical sites. (ECF No. 37 at 16.)

None of these details were conveyed to investors at the time, however. On July 18, 2023, BioVie issued a letter to shareholders, signed by Defendant Do, reporting on "tremendous progress" since the previous December and commenting on initial data collection. (*Id.* at 30-31 ("July 18, 2023 Letter to shareholders").) Among other things, the letter included the following:

> [T]he totality of the data we have shared lead me to be increasingly excited and optimistic about what we hope to see when our Phase 3 trial for NE3107 in Alzheimer's Disease (AD) reads out later this year . . . . As we approach data readout, I am increasingly optimistic about what we hope to see based on the totality of the data that we have disclosed. The data described above is suggestive that NE3107 may have an active epigenetic effect associated with improvements in inflammation [referring to Phase 2 trial as well]…"

(*Id*.)

D. August 2023 Audit

On August 8 and 9, 2023, GeoSera, Inc. ("GeoSera"), conducted a second for-cause audit at Site No. 145—the same site subject to the Pitts Audit in December 2022. (*Id.* at 13-14.) The GeoSera Audit, like the Pitts Audit, revealed serious data integrity

concerns. (*Id.*) Auditors made three critical observations, including that demographics and signature sections in MRI reports appeared to have been modified, that multiple MRI reports contained the same exact assessments for multiple patients, and that medical records contained discrepancies in demographic information and dates. (*Id.*) GeoSera auditors detailed issues in over 30 patients' medical records. (*Id.*) Other observations related to concerning record-keeping procedures, including overwriting reports, inconsistent notes, and missing MRI documentation. (*Id.*) And additional minor observations related to missing MRI location information in patient files. (*Id.*)

Taken together, these observations resulted in an "unsatisfactory" audit rating; GeoSera concluded that many patient files were "highly suspect" and contained source data that could not be validated, and that MRIs were not obtained in accordance with GPCs. (*Id.*) Auditors recommended further investigation to determine the cause of the missing or suspect data and to confirm whether the identified patients were eligible for final data analysis in the NM101. (*Id.*) And auditors further concluded that the CRO should have halted the Study at Site No. 145 and failed to do so despite more than a dozen monitoring visits. (*Id.*) Site Administrator Marichal and a CRO monitor, Jonathan Dominguez, attended the initial and closing audit meetings where auditors discussed these findings. (*Id.*)

On August 16, 2023, BioVie filed an annual report on Form 10-K. (*Id.* at 31-36 ("August 16, 2023, Form 10-K").) In the report, the Company stated the same expected timeline for primary study completion and again included statements explaining the role of CROs and the risk of delay in the event of noncompliance. (*Id.*)

E. Data Unblinding and Exclusion of Data from 15 Clinical Trial Sites

During the fall of 2023, BioVie continued to comment publicly on the Study's progress. (*Id.* at 36-37 ("September 8, 2023, Form 8-K") ("Current understanding provides optimism for the Phase 3 trial in Mild to Moderate Alzheimer's expected to read out in Q4 2023 . . . .").) On October 25, 2023, BioVie issued a press release announcing blinded data from NM101 and its presentation at the 16th Clinical Trials on Alzheimer's

Disease ("CTAD") conference. (*Id.* at 38 ("October 25, 2023, Press Release").) The press release included statements that "[t]he blinded data presented suggest that NE3107 is a biologically active compound…with some patients demonstrating an improvement after 30 weeks of treatment . . . as compared to baseline . . . ." (*Id.*) In addition, Defendant Palumbo commented that "The blinded data presented at CTAD show encouraging changes from baseline that would not typically be seen without a treatment effect," adding that this "provides us with confidence that NE3107 may show a clear benefit over placebo when the data from this trial is unblinded." (*Id.*) BioVie also noted in the press release that "the Company [wa]s currently resolving outstanding database queries." (*Id.*)

On November 1, 2023, Defendants held a conference call with investors to discuss the results of the Study, on which Defendants Do and Palumbo again expressed "cautious optimism" about the totality of the blinded data. (*Id.* at 39-40 ("November 1, 2023, Conference Call") ("[I]n looking at the totality of the data, we conclude that any NE3107 . . . appears to be having an impact on the cognitive biomarkers and end-to-end points that we've looked at in the trial . . . ").)

One week after the conference call, on November 8, 2023, BioVie filed a quarterly report on Form 10-Q, in which it disclosed that it had identified possible data integrity issues not just at Site No. 145, but at six total clinical sites enrolling a total of 128 patients. (*Id.* at 15 ("November 8, 2023 Form 10-Q").). BioVie told investors that "during routine monitoring of blinded data from our Phase 3 study . . . of NE3107, we uncovered what appears to be potential scientific misconduct and significant non-compliance with GCPs and regulation" at these six sites, and noted that it had alerted the FDA's office of scientific integrity. (*Id.*) The Company also updated its study protocol to exclude patients from affected sites and allow additional enrollment, pre-specify subgroup analyses, and finalize its primary endpoints. (*Id.* at 16.) BioVie told investors that "these findings of potential scientific misconduct and significant GCP violations may

call into question the rigor, robustness and validity of the entire data set . . . and may require additional clinical studies." (*Id.* at 16.)

Unfortunately, the data integrity issues ultimately extended even further, which became clear as the remainder of the Study's data was unblinded in the following weeks. On November 29, 2023, BioVie filed a current report on Form 8-K, attaching a corporate press release on top-line NM101 data and a copy of an investor presentation. (*Id.* at 15-16 (November 29, 2023, Form 8-K.) In the press release, BioVie disclosed that "[u]pon trial completion, the Company found significant deviation from protocol and Good Clinical Practice . . . violations at 15 sites (virtually all of which were from one geographic area)." (*Id.*) BioVie emphasized that the level of suspected impropriety was "highly unusual" and that as a result, BioVie had to exclude patients from all 15 of those sites. (*Id.*) This meant excluding 358 patients—over 80% of NM101's total enrollment (*Id.*) After excluding the problematic data, only 81 patients remained in the "Modified Intent to Treat (MITT)" population, and only 57 of those were in the per-protocol population. (*Id.*) As a result of the number of excluded patients, NM101 was ultimately "underpowered," failing to reach the level of statistical significance required to proceed towards FDA marketing approval. (*Id.* at 17.)

As to the circumstances leading to the discovery of anomalies at the newly-identified nine sites, Defendant Do stated on a conference call to investors (hosted the same day BioVie released the news) that when BioVie had started to unblind data, focusing on sub-group analyses (including demographic group analyses) recommended by Pantera, BioVie had noted further scientific anomalies: "The placebo patients are not expected to significantly and dramatically improve as we saw in the data from [this demographic group]" (*Id.* at 18-19 (November 29, 2023 Conference Call).) Defendant Do represented that the problem "turned out to be one and of the same in . . .virtually all patients from the demographic group" at the 15 problematic sites. (*Id.*) Explaining how such major issues arose, Do stated that various "confounding factors" contributed, citing BioVie's limited access to clinical sites at the height of the COVID-19 pandemic,

insufficiency of on-the-ground monitoring by third-party organizations responsible for doing so, and BioVie's assumption of good intent. (*Id.*) While Do stated he did not want to speculate further before an FDA investigation, he noted the possibility of a "phenomena [of] professional patients that may be part of what is going on here" (*Id.*)

On November 29, 2023, BioVie's stock was down more than 60% from the previous day's closing price. (*Id.* at 19.)

F. Procedural History

Lead Plaintiff Dr. Anthony Rinaldi and additional named plaintiff Mark Hill are BioVie investors representing a putative class of similarly-situated investors who purchased BioVie common stock between December 7, 2022, and November 28, 2023 ("Class Period").[7] (*Id.* at 1, 4.) On June 21, 2024, after related actions were consolidated (ECF No. 30), Plaintiffs filed the operative Amended Complaint (ECF No. 37). In Count one, Plaintiffs assert that all Defendants violated Section 10(b) of the Securities Exchange Act, 15 U.S.C. §§ 78j(b), and SEC Rule 10b-5, 17 C.F.R. § 240.10b-5, by deceiving investors into purchasing BioVie securities at artificially inflated prices. (ECF No. 37 at 52.) In Count two, Plaintiffs assert that Individual Defendants violated Section 20(a) of the Exchange Act, 15 U.S.C. §§ 78t(a), as controlling persons. (*Id.* at 52-53.) Plaintiffs request class certification and compensatory damages. (*Id.* at 56.)

III. DISCUSSION

Defendants move to dismiss the Amended Complaint under Federal Rules of Civil Procedure 12(b)(6) and 9(b). (ECF No. 38.) In conjunction with the Motion, Defendants filed a request for judicial notice. (ECF Nos. 39, 40, 41, 42, 43.) The Court first addresses the request for judicial notice and then turns to the Motion.

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[7]Between December 14 and 21, 2022, BioVie sold approximately 1.4 million shares of stock under its agreement with Cantor Fitzgerald and B. Riley Securities, generating roughly $15 million in cash—about one-third of BioVie's total liquidity. (*Id.* at 12.) Between December 21, 2022, and April 3, 2023, BioVie sold approximately 3.6 million additional shares to public investors, raising $19.8 million—roughly two-thirds of BioVie's total liquidity. (*Id.* at 12.)

A. Request for Judicial Notice

Defendants request that the Court consider 26 exhibited documents—more than 600 pages in total—in evaluating their 12(b)(6) Motion on the basis that these documents are incorporated by reference into the Amended Complaint and/or subject to judicial notice. (ECF No. 43.) *See Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007) (noting that when evaluating a Rule 12(b)(6) motion to dismiss a Section 10(b) claim, a district court "must consider the complaint in its entirety, as well as other sources courts ordinarily examine when ruling on Rule 12(b)(6) motions to dismiss, in particular, documents incorporated into the complaint by reference, and matters of which a court may take judicial notice").

The Court generally "may not consider material outside the pleadings when assessing the sufficiency of a complaint under Rule 12(b)(6)." *Khoja v. Orexigen Therapeutics, Inc.*, 899 F.3d 988, 998 (9th Cir. 2018). When "'matters outside the pleading are presented to and not excluded by the court,' the 12(b)(6) motion converts into a motion for summary judgment under Rule 56." *Id.* (quoting Fed. R. Civ. P. 12(d)). The Court may, however, consider exhibits attached to a complaint or matters subject to judicial notice under Federal Rule of Evidence 201 without converting the motion into one for summary judgment. *See id*. A federal court may properly take judicial notice of matters of public record, but it "cannot take judicial notice of disputed facts contained in such public records." *Id.* at 999. "[T]he unscrupulous use of extrinsic documents to resolve competing theories . . . risks premature dismissals of plausible claims that may turn out to be valid after discovery." *Khoja*, 899 F.3d at 998 ("This risk is especially significant in SEC fraud matters, where there is already a heightened pleading standard . . . ."). Under the incorporation by reference doctrine, the Court may consider documents "'whose contents are alleged in a complaint and whose authenticity no party questions, but which are not physically attached to the [plaintiff's] pleading.'" *In re Silicon Graphics Inc. Sec. Litig.*, 183 F.3d 970, 986 (9th Cir. 1999) (quoting *Branch v. Tunnell*, 14 F.3d 449, 454 (9th Cir.1994)). Unlike under the judicial notice doctrine, the

contents of documents incorporated into a complaint by reference may be considered for their truth. *See Khoja*, 899 F.3d at 1003. But "what inferences a court may draw from an incorporated document should also be approached with caution," and the documents' truth may not be assumed only to dispute facts in the complaint. *Id.*

The Court addresses each category of materials BioVie seeks to introduce in support of its Motion. First, Plaintiffs do not object to the Court's consideration of 13 exhibited documents for their contents, as these materials (which include SEC filings, conference call transcripts, and letters to shareholders) are undisputedly incorporated by reference in the Amended Complaint. (ECF Nos. 40-1, 40-2, 40-3, 40-6, 40-12, 40-13, 40-14, 41-15, 41-17, 41-22, 41-23, 41-24, 42-25.) *See Khoja*, 899 F.3d at 1003. The Court will thus consider the content of these materials where relevant. *See id.*

Second, Defendants request that the Court consider three documents which are not directly incorporated in the Amended Complaint but were either publicly filed or are readily available on BioVie's website. (ECF Nos. 40-8 (press release dated September 26, 2023), 41-16 (investor presentation accompanying conference call on November 1, 2023), 42-26 (September 27, 2022 Form 10-K).) The Court takes judicial notice of the existence of these public documents—and the fact that BioVie *made* the public statements contained therein—but will not judicially notice the truth of any statements therein to resolve factual disputes. *See Khoja*, 899 F.3d at 999. The Court recognizes the risk that Defendants may cherry-pick public statements supporting their position, without referencing public materials which run counter to their arguments. *See id.* (cautioning against the unscrupulous use of extrinsic documents to resolve competing theories). This concern is heightened because two of the most vital documents referenced in the Amended Complaint—the Pitts Audit and GeoSera Audit reports—are not part of the judicial notice request or otherwise available for the Court's review at this early stage. (ECF No. 45 at 3.)

Third, Defendants seek to judicially-notice two BioVie press releases which Plaintiffs argue are pre- or post-Class Period materials irrelevant to resolution of the

Motion. (ECF Nos. 40-11 (press release dated November 29, 2022), 41-19 (press release issued March 11, 2024), 45 at 6-7.) *See Stern v. Charles Schwab & Co., Inc.*, Case No. CV-09-1229-PHX-DGC, 2009 WL 3352408, at *4 (D. Ariz. Oct. 16, 2009). Although these press releases were issued outside of the Class Period, the Court finds it is appropriate to take limited judicial notice of their existence and the fact that (1) Defendants announced their decision to increase enrollment in the Study before the Class Period began, and (2) Defendants have stated their optimism about NE3107's ultimate viability after the Class Period. (ECF Nos. 38 at 19, 45.) Those facts are not subject to reasonable dispute because they are clear solely from the existence of the press releases, without requiring the Court to evaluate the accuracy of their contents.

Fourth, Defendants request that the Court consider three transcripts from healthcare conferences and webinars. (ECF Nos. 40-4 (transcript of session at Oppenheimer's Healthcare Conference on March 15, 2023), 40-5 (transcript of session at Cantor Fitzgerald Conference on September 26, 2023), 40-7 (transcript of BioVie webinar on September 7, 2023).) These documents were not filed with the SEC and are not otherwise part of the public record. Even if they were part of the public record, it is inappropriate for the Court to consider their contents to resolve disputed facts regarding Defendants' mental state and BioVie's good faith, and the Court declines to notice these materials. *See Khoja*, 899 F.3d at 999.

Finally, Defendants seek to notice materials in five[8] documents from third-party sources, including scientific journal articles on Alzheimer's Disease research and clinical trial procedures. (ECF Nos. 40-9, 40-10, 41-18, 41-20, 41-21.) Defendants primarily cite these articles in the Motion to support their descriptions of industry standards, and to provide a definition of "enrollment" in clinical trials. The Court declines to take judicial

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[8]In their opposition to the request for judicial notice, Plaintiffs address three additional articles referenced in Defendants' Motion but not included in the list of documents for which they seek judicial notice. (ECF No. 45 at 11.) To the extent Defendants ask the Court to judicially notice facts in these articles, the Court reaches the same conclusion and will not consider them for their truth.

notice of the contents of these articles to resolve disputed facts as to whether BioVie complied with industry norms or misrepresented enrollment. *See Von Saher v. Norton Simon Museum of Art at Pasadena*, 592 F.3d 954, 960 (9th Cir. 2010) ("Courts may take judicial notice of publications introduced to indicate what was in the public realm at the time, not whether the contents of those articles were in fact true.").

B. Motion to Dismiss

Under Section 10(b) of the Securities Exchange Act, it is unlawful "[t]o use or employ, in connection with the purchase or sale of any security . . . any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the Commission may prescribe." 15 U.S.C. § 78j(b). SEC Rule 10b-5 makes it unlawful to "make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading." 17 C.F.R. § 240.10b-5.

To state a securities fraud claim under Section 10(b) and Rule 10b-5, a plaintiff must allege "(1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation." *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 37-38 (2011). A complaint must, as always, "contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Khoja*, 899 F.3d at 1008 (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). But a securities fraud plaintiff must further satisfy the heightened pleading standards of both Rule 9(b) and the Private Securities Litigation Reform Act ("Reform Act"). *See Oregon Pub. Emps. Ret. Fund v. Apollo Grp. Inc.*, 774 F.3d 598, 603-04 (9th Cir. 2014); *Khoja*, 899 F.3d at 1008. Rule 9(b) requires a plaintiff to "state with particularity the circumstances constituting fraud" and applies to all elements of a securities fraud action. *Oregon Pub. Emps. Ret. Fund*, 774 F.3d at 605. *See* 15 U.S.C. § 78u-4(b)(1)(B); *id.* at § 78u-4(b)(2)(A). With respect to the scienter element, a plaintiff must also "state with particularity facts giving rise to a *strong*

inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2)(A) (emphasis added). *See Glazer Cap. Mgmt., L.P. v. Forescout Techs., Inc.*, 63 F.4th 747, 766 (9th Cir. 2023) ("Falsity is subject to a particularity requirement and *the reasonable inference* standard of plausibility set out in *Twombly* and *Iqbal*, and scienter is subject to a particularity requirement and a *strong inference* standard of plausibility."). While these pleading requirements are "formidable [ones]," the Court may not "transform them into impossible one[s]" at the motion to dismiss stage. *Id.*

Defendants argue that Plaintiffs fail to identify particularized sources underlying their allegations, and that they insufficiently allege falsity, scienter, and loss causation. (ECF No. 38.) Because the Court finds that Plaintiffs sufficiently plead each of these elements, the Court denies the Motion.

1. Allegations made on information and belief

As a preliminary matter, Defendants argue broadly that Plaintiffs' claims depend on unsupported allegations "made only on information and belief without a particularized basis or source as required by the Reform Act." (*Id.* at 15-16.) Defendants contend that without more detail or attribution to confidential witnesses with personalized knowledge, "Plaintiffs fail to offer any facts from which the Court could assess the credibility of their more specific allegations." (*Id.* at 16.) *See In re Blue Rhino Corp. Sec. Litig.*, Case No. CV 03-3495, 2004 WL 5681763, at *5 (C.D. Cal. Oct. 7, 2004).

Plaintiffs must "specif[y] each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading." *In re Atossa Genetics Inc Sec. Litig.*, 868 F.3d 784, 793-94 (9th Cir. 2017). Under the heightened pleading standards,"[i]f an allegation… is made on information and belief," a complaint must "state with particularity all facts on which that belief is formed." *Id.* (citing 15 U.S.C. § 78u-4(b)(1)). *See also Fanni v. Northrop Grumman Corp.*, 23 F. App'x 782, 784-85 (9th Cir. 2001). Whether Plaintiffs' allegations are divorced from their source is a holistic inquiry. *See id.* (noting that a court may weigh all relevant circumstances, sources of information, and corroborating details). An absence of confidential witness statements

or other similar materials is only part of the inquiry. *See, e.g.*, *Glazer Cap. Mgmt.*, 63 F.4th at 766-67 ("[I]f a complaint relies on a confidential witness and other factual information, the confidential witness need not reveal his sources provided the other facts provide an adequate basis for believing the defendant's statements were false.").

Here, Plaintiffs largely base their claim on public documents, Defendants' own statements, and audit reports—sources with corroborating details. With this in mind, the Court will consider the sufficiency of Plaintiffs' sources in its analysis of claim elements but will not make the sweeping conclusion that Plaintiffs wholly fail to provide the requisite particularity.

2. False or misleading statements

To survive dismissal, Plaintiffs must first allege with particularity that Defendants made a false or misleading statement of material fact or omitted to state a material fact. *See* 15 U.S.C. § 78u-4. A false statement is one that "directly contradict[s] what the defendant knew at that time." *Khoja*, 899 F.3d at 1008. A statement is misleading if it "would give a reasonable investor the 'impression of a state of affairs that differs in a material way from one that actually exists.'" *Berson v. Applied Signal Tech*, 527 F. 3d 982, 985 (9th Cir. 2008) (citing *Brody v. Transitional Hosps. Corp.*, 280 F.3d 997, 1006 (9th Cir. 2002)). *See also In re GlenFed, Inc. Sec. Litig.,* 42 F.3d 1541, 1547-49 (9th Cir, 1994) (requiring details about fraudulent statements, such as time, place, and content).

Securities laws "do not create an affirmative duty to disclose any and all material information." *Matrixx*, 563 U.S. at 44-45. "Disclosure is mandatory only when necessary to ensure that a statement made is not misleading." *In re Facebook, Inc. Sec. Litig.*, 87 F.4th 934, 948 (9th Cir. 2023), *cert. dismissed as improvidently granted sub nom. Facebook, Inc. v. Amalgamated Bank*, 604 U.S. 4 (2024). Nevertheless, "'once defendants cho[ose] to tout' positive information to the market, 'they are bound to do so in a matter that wouldn't mislead investors,' including disclosing adverse information that cuts against the positive information." *Schueneman v. Arna Pharms, Inc.*, 840 F.3d 698, 705-06 (9th Cir. 2016) (quoting *Berson*, 527 F. 3d at 987).

Plaintiffs allege that Defendants made eighteen false or misleading statements during the Class Period. (ECF No. 37.) These include statements "(1) detailing the numbers of patients enrolled in the Phase 3 Study and explaining why BioVie increased target enrollment in November 2022; (2) describing the expected timing of primary completion of the Study; (3) expressing optimism about blinded data; and (4) discussing risks related to the clinical trial process" (ECF No. 38 at 16-17.) Importantly, although the parties address statements based on their substantive category and not based on their chronology, the Court must also position them within an evolving context. Over the 11-month Class Period, as the NM101 trial progressed, the Amended Complaint suggests that BioVie gained information about data irregularities. Several challenged statements appear in BioVie's early-December 2022 communications, before the Pitts Audit. (*See* ECF No. 37 at 19-21.) Other statements appear in BioVie's communications over the winter of 2023, after the Pitts Audit but before clinical sites began to finish their patient-facing operations. (*See id.* at 22-27.) The next set appear in communications in the spring and summer of 2023, when BioVie began its review of some blinded data. (*See id.* at 27-31.) And the last statements were made during the late summer and fall of 2023, after the GeoSera Audit. (*Id.* at 31-40.) Where appropriate, the Court evaluates the parties' arguments with this timeline in mind.[9]

a. Enrollment statements

Plaintiffs allege that BioVie made various false or misleading statements describing NE3107 as "fully enrolled" and explaining the Company's decision to expand enrollment to 400 patients in December 2022.[10] (ECF No. 37.) Plaintiffs assert that

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[9]The Court does not address how its findings related to this timeline could impact the Class Period, as that is beyond the scope of the Motion and this order.

[10]Statements about enrollment appear in the December 7, 2022 Form 8-K and attachments (ECF No. 37 at 19-20 ("BioVie's Phase 3 trial in AD has fully enrolled the targeted 316 patients")); the February 10, 2023, Form 10-Q (*id.* at 22 ("[T]he Alzheimer Phase 3 study is approaching full enrollment")); the March 2, 2023, Press Release (*id.* at 25 (announcing that BioVie has "achieved its revised enrollment target of 400 patients")); the March 23, 2023 Form 8-K and attachments (*id.* at 26-27); the May 12,

these statements were inconsistent with internal information, and that "because of persistent patient fraud, 80% of the 'fully enrolled' patients should never have been enrolled in the study to begin with." (ECF No. 44 at 15.)

In their Motion, Defendants first argue that their enrollment statements were not misleading because Plaintiffs "fundamentally misunderstand[]" the meaning of "enrollment" in the clinical-trial context. (ECF No. 38 at 11.) They contend that in the biopharmaceutical industry, "enrollment" means only participants' initial agreement to participate in a clinical study, and sophisticated investors would "understand that statements specifying numbers of 'enrolled' patients did not guarantee that those patients had met (or in future would meet) the trial's eligibility criteria, that they would comply with or complete the trial protocol, or that they would not later dropout or be excluded from the trial analysis." (*Id.* at 11-12.) *See Abramson v. Newlink Genetics Corp*., 965 F.3d 165, 175 (2d Cir. 2020) (evaluating reasonable investor expectations based on "the customs and practices of the relevant industry"); *Tongue v. Sanofi*, 816 F.3d 199, 214 (2d Cir. 2016) (evaluating reasonableness from the perspective of sophisticated investors familiar with the FDA process). Plaintiffs argue that by announcing "full enrollment," BioVie implied that participants met the pre-specified enrollment criteria in the Study's protocol. (ECF No. 44 at 15.)

To support their position on the meaning of "enrollment" in the biopharmaceutical industry, Defendants point to several extrinsic articles (ECF No. 38 at 17-18 nn. 6-7), which the Court has already declined to judicially notice and will not consider here. But even assuming that a clinical trial's "full enrollment" does not foreclose the possibility that some participants may later be found to be ineligible and disenrolled, this does not mean BioVie's statements could not have been misleading. Regardless of the technical meaning of enrollment, the Court's objective inquiry into the perspective of the

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2023, Form 10-Q (*id.* at 29 ("[T]he Alzheimer Phase 3 study reached full enrollment")); the July 18, 2023, Letter to Shareholders (*id.* at 30-31 ("Our NM101 trial has been fully enrolled since February 2023")); the August 16, 2023, Form 10-K (*id.* at 31-36 ("[S]tudy is fully enrolled.")); and the September 8, 2023, Form 8-K (*id.* at 36-37).

reasonable investor is always contextual. *See Matrixx*, 563 U.S. at 38, 43 (citing *Basic Inc. v. Levinson*, 485 U.S. 224, 108 (1988)) (finding investors sufficiently pled a material misstatement regarding adverse effects of a cold medication, regardless of the statistical significance of the adverse reports concealed); *Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund*, 575 U.S. 175 (2015) ("[T]he analysis of whether [the statement is] misleading must address the statement's context…That means the court must take account of whatever facts Omnicare did provide about legal compliance, as well as any other hedges, disclaimers, or qualifications . . . .").

In the context of clinical trials, courts have sometimes held defendants liable for making misleading statements about the enrollment. *See, e.g.*, *Abramson*, 965 F.3d at 169, 171 (finding statements confirming the enrollment goal of "722 subjects with surgically resected pancreatic cancer ha[d] been met" misleading because the company was aware that some individuals had been improperly enrolled). Moreover, companies may misrepresent material information when they present positive developments and fail to disclose already-materialized doubt as to the certainty of those developments. *See, e.g.*, *Khoja*, 899 F.3d at 1010 (9th Cir. 2018) (finding that without disclosing high degree of uncertainty in data collected, "the 'surprising' 25 percent interim results [in a study] appeared more promising than Orexigen allegedly knew they were"); *Berson*, 527 F. 3d at 982 (finding plaintiffs pled falsity where company allegedly received stop-work orders from government clients but counted those orders as a "backlog" of work to be completed). *See also Medina v. Clovis Oncology, Inc.*, 215 F. Supp. 3d 1094, 1105 (D. Colo. 2017) (finding misleading statements where a company "failed to disclose that its presentation of efficacy data was based upon unconfirmed responses").

The Court agrees with Plaintiffs that the possibility of some patients being disenrolled in the normal course of a clinical trial is "materially different from knowing in fact that large swaths of patients . . . had no business being in the trial to begin with." (ECF No. 44 at 16.) The Court now considers whether Plaintiffs' allegations reasonably lead to an inference of enrollment deficits on a material scale.

With the alleged facts, the Court cannot reasonably infer that the enrollment statements from early December 2022, taken alone, were materially false or misleading. (*See* ECF No. 37 at 19-21 ("BioVie's Phase 3 trial in AD has fully enrolled the targeted 316 patients").) These statements were made *before* the Pitts Audit on December 28 and 29, 2022. And although Plaintiffs allege in general terms that BioVie became aware of possible data concerns during its earlier DSMB review preparations, no particularized facts suggest data integrity issues significant enough to materially impact enrollment earlier than the Pitts Audit. There are only vague allegations as to the nature of the concerns which led to the Pitts Audit in the first place, and it is not entirely clear whether BioVie or another party initiated that audit. That BioVie ultimately discarded data from up to 15 different sites does not, in hindsight, make these early statements misleading—let alone materially so. *See Brody*, 280 F.3d at 1006.

For the same reasons, there are insufficient particularized facts to support an inference that BioVie's December 2022 statements explaining the increase in target enrollment from 316 to 400 patients "misrepresented the reasons for needing or wanting additional data." (ECF No. 44 at 15-17.) By early December 2022, BioVie had already announced that it would forego interim DSMB review and increase enrollment in the Study, citing the fact that the Company had finished enrolling 316 patients before 50% of enrolled patients completed the trial. (ECF No. 40-2 at 14, 29 (explaining Study protocol for DSMB interim review).) BioVie maintained the same explanation in later filings. (*See* ECF Nos. 37 at 25 (March 2, 2023 Press Release), 40-6.) Plaintiffs fail to plead specific facts suggesting that Defendants were aware of data issues significant enough to necessitate additional enrollment before the Pitts Audit occurred, and Plaintiffs' contention that BioVie concealed the "real" reasons for increased enrollment would require the Court to resort to speculation.

As to BioVie's *post*-Pitts Audit statements on enrollment, however, Plaintiffs adequately allege with particularity that an objectively reasonable investor could have been misled; undisclosed information about the risk of pervasive patient ineligibility

could have "significantly altered the 'total mix' of information made available'" such as to "raise a reasonable expectation that discovery will reveal evidence" satisfying the materiality requirement." *Matrixx*, 563 U.S. at 38, 43 (quoting *Basic Inc. v. Levinson*, 485 U.S. 224, 108 (1988)). After December 2022, alleged findings from the Pitts Audit at Site No. 145, which had been placed under an enrollment hold, gave reason to doubt that the patients enrolled in that site should have been included in the Study at all. For example, "patient medical records appeared to be falsified so as to render patients 'eligible' for the NM101 study when in fact they were not," and duplicative and tampered-with Alzheimer's Disease diagnosis records cast doubt on whether the enrolled patients actually had Alzheimer's Disease at all. (ECF No. 37 at 10-11.) According to the Amended Complaint, the Audit revealed severe deficiencies which merited the auditors' recommendation that NM101 cease enrollment and close the site. (*Id.*) Site No. 145 was not a peripheral Study location: it was NM101's principal clinical trial site, where 45 patients—more than 10% of the Study's total revised target enrollment—were enrolled by the end of 2022. (*Id.* at 9.) And although Plaintiffs do not allege that any additional enrollment occurred at Site No. 145 after December 2022, there are no facts to suggest BioVie took corrective action to ensure compliance in response to the Pitts Audit.

A plausible inference that Defendants' enrollment statements were misleading becomes stronger as the Court considers the statements made in the summer and fall of 2023. BioVie representatives have themselves stated that, before the second for-cause audit at Site No. 145, the Company observed unusual data patterns in blinded data from *multiple* sites, leading to its retention of additional CROs. (*Id.* at 16-17.) And the GeoSera Audit allegedly confirmed serious enrollment eligibility issues at Site No. 145 concerningly similar to those that had appeared in the Pitts Audit months earlier, including, *inter alia*, suspect findings in at least 30 patient files. (*Id.* at 13-14.) Moreover, Defendants made statements affirming NM101's full enrollment over the summer and fall of 2023 while *also* expressing optimism about preliminary data, even though

increasing doubts about data were being investigated. (*Id.* at 30-31 (July 18, 2023, Letter to Shareholders).) And Defendants further reiterated that "[t]he program is fully enrolled" after the GeoSera Audit. (*Id.* at 31-32 (August 16, 2023, Form 10-K).)

BioVie argues that any data integrity concerns impacting enrollment were confined to Site No. 145, and that "neither BioVie's later decision to exclude patients from 15 clinical sites due to apparent misconduct, nor the Site No. 145 Audits, establish that any particular patients were ineligible to participate, only that their data could not be trusted" (ECF No. 38 at 12.) But untrustworthy patient data is a serious concern and such broader integrity issues would not appear to be limited to a particular patient's eligibility to participate. The Court also notes that numerous facts alleged in the Amended Complaint suggest that Site No. 145 was not particularly isolated from other sites.[11] "[A] sufficient number of improper enrollments," including the enrollment of ineligible individuals, can "naturally and predictably affect a trial's statistical integrity." *Abramson*, 965 F.3d at 179-80. In short, BioVie's comments about the Study reaching its "enrollment target" plausibly contributed to an impression that the Study, based on its enrollment protocol, was on-track to produce results supporting FDA approval on a predictable timeline.

In sum, the Court finds Plaintiffs have adequately pleaded the falsity element of their Section 10(b) claim as to the enrollment statements. Plaintiffs fail, however, to allege sufficient facts to support a particularized inference regarding any of the statements from December 2022. *See Abramson*, 965 F.3d at 172.

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[11]High-level personnel involved in NM101, including the Principal Investigator, were present at the Pitts Audit closing meeting. (*Id.* at 13-14.) And Defendants acknowledge that all 15 of the sites from which data ultimately had to be excluded were located in the same geographic region. Some of the concerns allegedly identified in the Pitts Audit—including concerns about data accuracy for one demographic group, translations of study materials, and unusual referrals from a regional medical office—might reasonably be expected to raise questions extending beyond the single site.

b. Target completion and data readout statements

Plaintiffs also allege that BioVie made false or misleading statements about the expected timeline for data collection and release of topline Study data. (ECF No. 37.)[12] Defendants argue that these are true and not misleading statements of opinion under the Supreme Court's standard in *Omnicare*, 575 U.S. 175, and that they are forward-looking statements protected by the Reform Act's safe harbor. (ECF No. 38 at 19-21.)

In general, "'expressions of optimism [and] projections about the future' are quintessential opinion statements." *Martin v. Quartermain*, 732 F. App'x 37, 40 n.1 (2d Cir. 2018) (quoting *In re Int'l Bus. Machs. Corp. Sec. Litig.*, 163 F.3d 102, 107 (2d Cir. 1998)). To plead the falsity of opinion statements under *Omnicare*, a plaintiff may rely on a theory of material misrepresentation (alleging both that "the speaker did not hold the belief she professed" and that the belief is objectively untrue); a theory that "a statement of fact contained within an opinion . . . is materially misleading"; or a theory of omission (alleging "facts going to the basis for the issuer's opinion . . . whose omission makes the opinion statement at issue misleading to a reasonable person reading the statement . . . in context"). *Atossa*, 868 F.3d at 801-02 (citing *Omnicare*, 575 U.S. at 194-95). *See also City of Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Align Tech., Inc.*, 856 F.3d 605, 615-16 (9th Cir. 2017).

The Court is skeptical of BioVie's categorization of the data readout statements as purely opinion statements (ECF No. 38 at 13-15), where many arguably convey relative certainty as to the timeline of Study completion (*See* ECF No. 37 at 21-22). More importantly, the statements involving data readout mostly appear in *combination*

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[12]Statements about anticipated study completion appear in the December 7, 2022, Form 8-K and attachments (ECF No. 37 at 21 ("[D]ata readout anticipated mid-2023")); the February 10, 2023 Form 10-Q (*id.* at 22 ("The Company is targeting primary completion of this study in the third quarter of calendar year 2023")); the March 2, 2023, Press Release (*id.* at 25 ("The Company anticipates announcing top line results from the study in October 2023….")); the March 23, 2023, Form 8-K and attachments (*id.* at 26-27; the May 12, 2023 Form 10-Q (*id.* at 29 ("The Company is targeting primary completion of this study in the fourth quarter of calendar year 2023")); the August 16, 2023, Form 10-K (*id.* at 31-36); and the September 8, 2023, Form 8-K (*id.* at 36-37).

with the enrollment statements. (*See, e.g.*, *id.* at 25 (announcing the Study as *fully enrolled* and then commenting that "[t]he Company anticipates announcing top line results from the study in October 2023").) Reviewing the data readout statements in context—rather than isolating them from other nearby clauses—these statements can reasonably be interpreted as part of an update on the present status of the Study.

Regardless, the Court finds that the statements are plausibly actionable under *Omnicare*. BioVie argues that Plaintiffs fail to state facts suggesting that the Company did not believe its own estimates as to when the Study was likely to reach primary completion (under a material misrepresentation theory) nor any contemporaneous omitted facts (under an omissions theory). (ECF No. 38 at 20.) *See Omnicare*, 575 U.S. at 184-86. The Court disagrees, particularly as to the latter theory. Readout statements following the Pitts Audit plausibly omit significant contemporaneous facts about BioVie's "inquiry into" underlying data issues, rendering the anticipated dates for study completion improbable and bolstering an inaccurate impression about the strength of the Study and its data.[13] *See id. See also Glazer*, 63 F.4th at 768-69 (finding sales pipeline statements "did not reflect the actual state of [the company's] affairs at the time" when some of the "technical wins" described in statements were actually illusory).

As with the enrollment statements, a plausible inference of falsity or misrepresentation is stronger with regard to the statements made later in the Class Period, when as data collection was completed, BioVie recognized potential discrepancies, and issues continued unabated at Site No. 145. (*See* ECF No. 37 at 31-36 (statement on August 16, 2023, maintaining that BioVie expected data completion in the fourth quarter after the GeoSera Audit).) Whether Defendants "simply believed" their predictions, especially those made later in the Class Period, involves factual questions

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[13]Importantly, however, there are inadequate facts to support that readout statements included in BioVie's early December 2022 communications were misleading, for the same reasons it laid out in its discussion of the December 2022 enrollment statements.

that cannot be resolved at this stage (and an omission may be misleading regardless of Defendants' beliefs). *See Omnicare*, 575 U.S. at 176. The fact that primary data completion did ultimately occur in November 2023 does not support the truthfulness of the prior readout statements, when the bulk of the primary data revealed at that time was unusable. *See Matrixx*, 563 U.S. at 38, 43.

Defendants further argue that the Reform Act's safe harbor protections for forward-looking statements apply. (ECF No. 38 at 15.) Under the Reform Act, there is no liability for a forward-looking statement to the extent that it is (i) identified as such and accompanied by meaningful cautionary statements, (ii) immaterial, or (iii) made without actual knowledge that it was false or misleading. *See Wochos v. Tesla, Inc.*, 985 F.3d 1180, 1189 (9th Cir. 2021). Defendants argue that the readout statements are protected under two prongs: first, they were identified as forward-looking and accompanied by cautionary language, and second, no facts suggest that Defendants did not actually believe the trial would be completed on the identified timeline. (ECF No. 38 at 15.) As to the first argument, the Court agrees with Plaintiffs that because the statements were largely integrated into discussions of *current* conditions and the progress of the Study, they were not purely forward-looking. In addition, "cautionary language" is not meaningful if it "discusses as a mere possibility a risk that has already materialized." *Glazer*, 63 F.4th at 781. To the extent BioVie made risk disclosures, those disclosures are broad; they leave open the question of whether BioVie failed to disclose materialized risks. As to the second argument, the Court has already discussed alleged facts which may have undermined BioVie's belief in the accuracy of its timeline.

In sum, the Court finds that Plaintiffs have sufficiently pleaded that some of BioVie's data readout and anticipated timeline statements, viewed alongside other contemporaneous comments to investors, are misleading.

c. Statements interpreting blinded data

The next category of statements includes those interpreting preliminary blinded data and expressing optimism about study results. (ECF No. 38 at 15-17.) Defendants

assert that Plaintiffs cannot support a Section 10(b) claims as to these statements because "[r]easonable persons may disagree over how to analyze data." (*Id.* at 22). *See In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510, 543 (S.D.N.Y. 2015), *aff'd sub nom. Tongue*, 816 F.3d at 199. They further argue that "vague statements of optimism" and "puffery" are non-actionable. (ECF No. 38 at 22.) *See Police Ret. Sys. of St. Louis v. Intuitive Surgical, Inc.*, 759 F.3d 1051, 1060 (9th Cir. 2014).

Statements addressing preliminary data and results appear in communications made on four dates between March and November 2023. (*See* ECF No. 37 at 26-27 (March 23, 2023 Form 8-K); 30-31 (July 18, 2023 Letter to Shareholders); 38 (October 25, 2023 Press Release); 39-40 (November 1, 2023 Conference Call).) On March 23, 2023, BioVie commented primarily on patients' baseline data. (*Id.* at 28 ("Blinded baseline data show evidence of metabolic inflammation in amyloid β positive and negative, and APOE4 positive and negative subjects . . . ."). On July 18, 2023, Defendant Do made more in-depth comments, stating the following in his Letter to Shareholders.

> [T]he totality of the [Phase 2 and blinded baseline Phase 3] data we have shared lead me to be increasingly excited and optimistic about what we hope to see when our Phase 3 trial . . . reads out later this year…As we approach data readout, I am increasingly optimistic about what we hope to see based on the totality of the data that we have disclosed.

(*Id.* at 30.) On October 25, 2023, BioVie issued a press release which included additional detail.

> The blinded data presented suggest that NE3107 is a biologically active compound exerting potential effects as observed by biomarker, imaging, cognitive and functional assessments. Population changes from baseline were observed, with some patients demonstrating an improvement after 30 weeks of treatment with the double blinded oral study drug (NE3107 or matched placebo) as compared to baseline, while many were also observed to have worsened, which is consistent with the natural progression of the disease . . . .
> The blinded data presented at CTAD show encouraging changes from baseline that would not typically be seen without a treatment effect, which provides us with confidence that NE3107 may show a clear benefit over placebo when the data from this trial is unblinded in the coming weeks.

(*Id.* at 38). Finally, on November 1, 2023, Defendant Do made the following comments.

> [W]e presented the data that we had as of October 18 from roughly 322 subjects, whose data were verified or in the process of being verified and cleaned as of this date. . . . And in looking at the totality of the data, we conclude that any NE3107 appears to be biologically active and that it appears to be having an impact on the cognitive biomarkers and end-to-end points that we've looked at in the trial."

(*Id.* at 39-40.)

In general, statements amounting to "mere corporate puffery" are non-actionable. But while "optimistic, subjective assessment hardly amounts to a securities violation," it is "uncontroversial" that not all statements of optimism fall within the category of feel-good puffery, and that "general statements of optimism, when taken in context, may form a basis for a securities fraud claim." *Compare Police Ret. Sys. of St. Louis*, 759 F.3d at 1060 (finding that vague statements about potential for market growth amounted to puffery), *with Warshaw v. Xoma Corp*., 74 F.3d 955 (9th Cir.1996) (finding a company made material representations by repeating assurances that FDA approval was imminent). *See also Khoja*, 899 F.3d at 1010 (reporting "the 'surprising' 25 percent interim results" was misleading when the report made the results appear more promising than Orexigen knew they were"); *Berson*, 527 F. 3d at 985**.**

The statements at issue here are not merely puffery or otherwise non-actionable opinions. First, several of these statements or major portions thereof do not express opinions at all, but rather convey objective conclusions about blinded data. (ECF No. 37 at 28 ("Blinded baseline data show evidence of metabolic inflammation…."); *id.* at 38 ("Population changes from baseline were observed, with some patients demonstrating an improvement after 30 weeks of treatment with the double blinded oral study drug.") *See In re QuantumScape Sec. Class Action Litig.*, 580 F. Supp. 3d 714, 739 (N.D. Cal. 2022) (holding that statements expressing certainty without opinion-qualifying language such as "I think" or "I believe" were not opinion statements).

Second, even to the extent the relevant statements all or partially constitute opinions, Plaintiffs' particularized factual allegations going to contemporaneous data integrity issues make these statements distinguishable from mere vague statements of

optimism. *See, e.g.*, *In re Cornerstone Propane Partners, L.P.*, 355 F.Supp.2d 1069, 1087 (N.D. Cal. 2005). "Where a defendant specifically references data and expresses optimism, the court will allow these statements to survive because either the defendant (1) read the relevant data and expressed optimism despite knowing the [creditability of study data] w[as] not promising [] or (2) did not read the relevant data but was representing to shareholders that he had, and expressed unfounded/blind optimism, which in itself is misleading." *Luo v. Spectrum Pharms., Inc.*, Case No. 2:21-cv-01612-CDS-BNW, 2024 WL 4443323, at *11 (D. Nev. Oct. 7, 2024).

Here, BioVie commented on the "baseline data" and patient improvement when it allegedly already knew or should have known of a significant risk that data integrity issues made those baseline numbers suspect. Indeed, part of the motivation for additional data verification efforts over the summer of 2023 was that BioVie itself noticed "unexpected" changes from baseline (ECF No. 37 at 16-19), especially in one demographic group. In addition to commenting on baseline data, BioVie also commented on NE3107's efficacy, implying a "clear benefit over a placebo" when there was reason to question this. BioVie argues that until the data was fully unblinded in mid-November 2023, the Company did not suspect the hoped-for scattering effect in the data reflected scientific misconduct, rather than drug efficacy. (ECF No. 38 at 23.) But even assuming BioVie believed its own optimistic statements, Plaintiffs can "allege that a statement of opinion, without providing critical context, implied facts that can be proven false." *Abramson*, 965 F.3d at 175.

Finally, BioVie's disclosure that "the Company is currently resolving outstanding database queries," on October 25, 2023 (ECF No. 37 at 38) does not resolve the issue in BioVie's favor. Read in context, Defendants' reference to "database queries" does not even definitely imply that data *concerns* have emerged—the statement could imply simple run-of-the-mill data review. Accordingly, the Court finds that Plaintiffs have sufficiently pleaded falsity here.

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d. Statements disclosing risk

The last set of statements are BioVie's compliance and risk disclosures, which Plaintiffs assert misled investors by presenting risks as merely potential when they had already materialized. (ECF No. 38 at 23-25.) Defendants argue that without the benefit of hindsight, no contemporaneous facts suggested a materialized risk of data insufficiencies "so severe they could cause regulatory denial or delay" at the time the challenged statements were made. (*Id*.)

The Compliance and risk disclosure statements at issue appear in BioVie's February and August 2023 Form 10-Ks. (ECF No. 37 at 23-24, 33-35.) In the February filing, BioVie included the following.

> If we or any of these third parties fail to comply with applicable cGCPs or fail to enroll a sufficient number of patients, we may be required to conduct additional clinical trials to support our marketing applications. . . .
> [I]f the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements…our clinical trials may be extended, delayed, or terminated.

(ECF No. 37 at 23-24.) BioVie's August 16 filing included similar risk language, plus additional language on FDA compliance, such as the following.

> The process required by the FDA before a drug…may be marketed in the United States generally involves the following:…Performance of adequate and well-controlled human clinical trials according to the FDA's current good clinical practices, or GCPs, to establish the safety and efficacy of the proposed drug . . . .

(ECF No. 37 at 33-35.)

Defendants argue that these statements are distinguishable from *Facebook*, 87 F.4th 934,[14] and other cases involving failure to disclose already-materialized risks

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[14]In *Facebook,* the Ninth Circuit addressed various risk disclosure statements made by Facebook before and after news announcements regarding Cambridge Analytica's long-term improper access to Facebook user data, including statements describing improper disclosure of data as a "purely hypothetical risk that could harm the company if it materialized," in a Form 10-K. *See* 87 F.4th at 941, 945. The court found that falsity was adequately pleaded because at the time Facebook made the relevant statements, the risk of improper data disclosure had already materialized; "Facebook employees flagged Cambridge Analytica in September 2015 for potentially violating Facebook's terms." *Id.*

because no significant risk of severe data insufficiencies was apparent from for-cause audits cabined to only one site. But Defendants' attempts to show that their risk statements were robust and specific are unsuccessful. It is true that a risk of regulatory delay does not necessarily materialize as soon as the first mere inklings of data discrepancies are discovered. *See Terenzini v. GoodRx Holdings, Inc.*, Case No. LA CV 20-11444-DOC-MAR, 2022 WL 2189592, at *4 (C.D. Cal. June 9, 2022). Nevertheless, as Plaintiffs note, a risk may materialize before its consequences. And a disclosure obligation does not only arise at the point where a risk amounts to statistical significance. *See Matrixx*, 563 U.S. at 38-43. Here, Plaintiffs plead with particularity that while BioVie used hypothetical language to disclose risks of CRO misconduct and delay, failure to comply with GCPs, and insufficient data, the Company had contemporaneous access to the Pitts Audit findings and (by the time of its August 16, 2023, Form 10K) the GeoSera Audit findings. *See Facebook*, 87 F.4th at 941; *Khoja*, 899 F.3d at 1010 ("[T]elling investors that the data might change is different from saying the data . . . is likely to change."). Moreover, hypothetical warnings about delay appear more misleading alongside statements regarding the Study's full enrollment, target completion, and promising initial data.

However, Plaintiffs fail to demonstrate how statements explaining *general* FDA procedures and compliance rather than disclosing risk (*see, e.g.*, ECF No. 37 at 33-35 ("The process required by the FDA before a drug . . . may be marketed . . . generally involves the following….")) are misleading. These compliance statements are part of a background overview of the U.S. development process, rather than Study-specific disclaimers which would lead an investor to believe BioVie was assuring compliance. Even though the inclusion of this regulatory information may be relevant to analysis of an investor's perception of risk disclosures (for example, regarding the possibility of judicial sanctions), the statements do not independently support a Section 10(b) claim.

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In sum, Plaintiffs plausibly allege the falsity element as to BioVie's risk disclosure statements. But statements solely addressing background on FDA procedures are not themselves bases for a Section 10(b) claim.

3. Scienter

Defendants next argue that Plaintiffs' Section 10(b) claim should be dismissed because they fail to plead scienter. (ECF No. 38 at 25-29). *See Matrixx*, 563 U.S. at 35-38 (describing requirement for scienter); *Glazer*, 63 F.4th at 766. The Court finds that Plaintiffs have alleged sufficient particularized facts supporting scienter.

To plead scienter, a plaintiff must "state with particularity facts giving rise to a strong inference" that a defendant acted with "an intent to deceive, manipulate, or defraud" or with "deliberate recklessness."[15] 15 U.S.C. § 78u-4(b)(2). *See also Webb v. Solarcity Corp.*, 884 F.3d 844, 851 (9th Cir. 2018). The inquiry is whether "*all* of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard." *Tellabs*, 551 U.S. at 310-11 (emphasis in original). In order to plead a "strong inference," a plaintiff must plead facts "rendering an inference of scienter *at least as likely as* any plausible opposing inference." *Id.* (emphasis in original). "The inference that the defendant acted with scienter need not be irrefutable, *i.e.,* of the 'smoking-gun' genre, or even the 'most plausible of competing inferences' but it 'must be more than merely reasonable or permissible—it must be cogent and compelling.'" *Id.* at 324 (internal citations omitted).

Defendants argue that Plaintiffs cannot support scienter because "[v]iewed holistically, the most reasonable inference to be drawn from the pleaded facts is that Mr. Do and Dr. Palumbo truly were optimistic about the blinded data and believed the Study was on track for a positive result right up until the data was unblinded and revealed suspected fraud on an unprecedented scale" (ECF No. 38 at 26-29.) Defendants

[15]"Deliberate recklessness" requires "an extreme departure from the standards of ordinary care" that presents "a danger of misleading buyers or sellers" that "is so obvious" that the spokesperson "must have been aware of it. *Glazer*, 63 F.4th at 765 (quoting *Schueneman v. Arena Pharms., Inc.*, 840 F.3d 698, 705 (9th Cir. 2016)).

specifically emphasize that (1) neither Do nor Palumbo is alleged to have made suspicious stock sales; (2) routine corporate motives to maintain working capital and a positive image with investors are insufficient to support scienter; (3) Plaintiffs do not proffer any confidential witnesses, contemporaneous documents, or other circumstantial evidence to show that Defendants Do or Palumbo intended to deceive investors; and (4) Plaintiffs' additional scienter allegations that "BioVie tried to conceal, whitewash, and ignore" the Site No. 145 audits do not support scienter. (*Id*.) The Court considers each of these arguments, weighing competing inferences. *See Tellabs*, 551 U.S. at 311.

First, the Court finds that Defendants overstate the significance of the fact that Individual Defendants did not make unusual stock sales during the class period. (ECF No. 38 at 26.) While "personal financial gain may weigh heavily in favor of a scienter inference[, t]he absence of a motive allegation . . . is not fatal for allegations must be considered collectively." *Tellabs*, 551 U.S. at 310. An insider making "rosy characterizations of company performance to the market while simultaneously selling large percentages of his holdings" may create a strong inference of fraudulent intent, *Lipton v. Pathogenesis Corp*., 284 F.3d 1027, 1036 (9th Cir. 2002), and lack of stock sales may "detract from a scienter finding," *Webb*, 884 F.3d at 856. But it does not follow that an *absence* of suspicious sales automatically precludes scienter. *See In re Rigel Pharms., Inc. Sec. Litig.*, 697 F.3d 869, 884 (9th Cir. 2012) (finding defendants' conduct concerning their own stock inconsistent only with a theory that *personal financial motives* established scienter). Defendants argue they would have been expected to capitalize on artificially inflated stock prices had they been aware that data was irreparably compromised. (ECF No. 38 at 26.) But Plaintiffs allege primarily that Defendants "conceal[ed] of the truth to obtain millions in in financing from public investors." (ECF No. 44 at 30.) Whether or not Individual Defendants sold stock during the Class Period is not necessarily relevant to that issue.

Second, Defendants argue that dismissal is appropriate because Plaintiffs fail to allege any personal motive with other than "BioVie's need for working capital and . . .

[to] maintain a successful image with investors," which is too generic to support scienter. (ECF No. 38 at 26-27.) "[A] desire to raise company financing can be probative of a motive to defraud investors." *In re Vantive Corp. Sec. Litig.*, 283 F.3d 1079, 1097 (9th Cir. 2002). But this alone is not enough: "[A]llegations of routine corporate objectives such as the desire to obtain good financing and expand are not, without more, sufficient." *Rigel Pharms.*, 697 F.3d at 884. Plaintiffs argue that the circumstances here amount to "more" because BioVie conducted capital raises at a time when NE3107 was particularly vital to the Company's long-term viability as the Company's only drug undergoing a phase 3 trial. (ECF No. 44 at 30.) BioVie's 2022 and 2023 capital raises were the foundation of most of the Company's liquidity. (ECF No. 37 at 12.)

The fact that delays or failures in NM101's testing could make a disproportionate impact on BioVie's overall financial status in the near term strengthens the inference of a possible motive to conceal information—or at least to delay informing investors about materialized risks until it became certain those risks could not be counteracted behind the scenes. *See, e.g.*, *In re Ibis Tech. Secs. Litig.*, 422 F.Supp.2d 294, 317 (D. Mass. 2006) (weighing a financing motive where financing was necessary to ensure a company would not "run out of cash"); *Howard v. Everex Sys., Inc.*, 228 F.3d 1057, 1064 (9th Cir. 2000). These circumstances are distinguishable from those involving generic corporate motives less integral to the core of corporate financial status. *See, e.g.*, *Rigel*, 697 F.3d at 884 (finding inadequate general contentions that company was seeking a partner and hoping to raise capital for its future longevity).

Considering the centrality of NE3107 to BioVie's financial integrity, a reasonable person could make a cogent inference of at least deliberate indifference, especially in conjunction with separate particularized allegations that (1) the Pitts and GeoSera Audits revealed concerns significant enough to merit recommendations to cease enrollment and/or close the Study's primary clinical site; (2) BioVie took actions to initiate site review and follow-up after itself identifying discrepancies in the blinded data, while continuing to tout early Study results; and (3) the ultimate misconduct at 15 patient

sites reflected the same general problems identified in the Pitts Audit almost a year prior. *See Matrixx*, 563 U.S. at 49 (finding allegations gave rise to "compelling" inference that "Matrixx elected not to disclose adverse event reports not because it believed they were meaningless but because it understood their likely effect on the market").

Under the comparative scienter inquiry, the Court must also weigh inferences in BioVie's favor. *See Tellabs*, 551 U.S. at 324. Here, a reasonable person could also make a cogent opposing inference that Defendants acted in good faith—believing in the viability of the NE3107, taking affirmative steps, and promptly disclosing their discovery of patient fraud to both the FDA and investors. Nevertheless, while a competing inference of nonfraudulent intent may be reasonable or even compelling, the Court cannot conclude on balance that a good-faith inference is *more* compelling than an inference that Defendants acted with intent or deliberate recklessness. *See id*. (no "smoking gun" required). Defendants argue that they—like investors—were the unsuspecting victims of an extraordinarily unusual pattern of patient fraud occurring on the watch of third parties. But Defendants also contend that they acted in good faith by taking unusually thorough steps to investigate data discrepancies. Without the benefit of discovery, these assertions seem to run counter to one another—Defendants assert they were proactive behind the scenes but nevertheless completely taken by surprise. And even if, as Defendants emphasize, Defendants believed and continue to believe in the ultimate viability of NE3107, good intentions supporting the overarching endeavor do preclude the possibility of recklessness along the way.

Nor does Defendants' third argument—that Plaintiffs fail to support their scienter allegations with confidential witness statements or other circumstantial evidence—alter the Court's analysis. Defendants assert that Plaintiffs rely improperly on assumptions about what Individual Defendant' knew based on their positions of authority within the Company. (ECF No. 38 at 27.) It is true that "[w]here a complaint relies on allegations that management had an important role in the company but does not contain additional detailed allegations about the defendants' actual exposure to information, it will usually

fall short of the PSLRA standard." *S. Ferry LP, No. 2 v. Killinger*, 542 F.3d 776, 784-85 (9th Cir. 2008). Here, however, Plaintiffs plead the contents of the Pitts and GeoSera Audit reports in detail; Defendants do not contest the existence of these reports. *See Nursing Home Pension Fund, Loc. 144 v. Oracle Corp.*, 380 F.3d 1226, 1230 (9th Cir. 2004) ("The most direct way to show . . . that the party making the statement knew that it was false is via contemporaneous reports or data, available to the party . . . "). Moreover, Defendants *themselves* made statements indicating personal exposure to the data itself, which would almost certainly include exposure to audit reports. (*See, e.g.*, ECF No. 37 at 38 (comment from Palumbo that "The blinded data presented at CTAD show encouraging changes from baseline"); 39-40 (statement from Palumbo interpreting data); 17-18 (comment from Do on how BioVie began observing discrepancies in the blinded data).) And in the context of a small corporation's lead drug trial, it would be unreasonable to believe Individual Defendants remained in the dark. *See S. Ferry LP*, 542 F.3d at 785-86 ("[A]llegations [regarding management's role in a company] may conceivably satisfy the PSLRA standard in a more bare form . . . in rare circumstances where the nature of the relevant fact is of such prominence that it would be 'absurd' to suggest that management was without knowledge of the matter.").

Defendants' final argument relates to Plaintiffs' additional scienter allegations that BioVie tried to conceal, whitewash, and ignore the Site No. 145 audits. Defendants contest the allegation that after the GeoSera Audit, Defendant Do told one of BioVie's medical monitors, Dr. Osman, "that he wanted to disregard the audit findings and proceed with data as it was" and that BioVie executives then turned to a different auditor "who was willing to overlook the data validity issues." (ECF No. 37 at 42-43.) Defendants argue this "makes no sense" because BioVie ultimately took action to report misconduct to the FDA. (ECF No. 38 at 28.) They further assert that Plaintiffs fail to plead a source regarding the conversation. (*Id.*) But here again, Defendants overstate the rigidity of the personal knowledge requirement, which allows for various indicia of reliability. *See, e.g.*, *In re Splash Tech. Holdings, Inc. Sec. Litig.*, 160 F. Supp. 2d 1059,

1070 (N.D. Cal. 2001). Unlike in many cases involving confidential witnesses, it appears reasonable that as a medical monitor, Osman would be positioned to know the information alleged, and there are no comparable issues of multi-layered hearsay. *See Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 995-998 (9th Cir. 2009) (finding a complaint lacked facts suggesting requisite personal knowledge because "[s]ome of the confidential witnesses were simply not positioned to know the information alleged," and "many report only unreliable hearsay"). Even setting this aside, the Court does not rely unduly on the single allegation regarding Osman.

Because the Court concludes that a compelling inference that Individual Defendants acted with minimum deliberate recklessness is at least as strong as an opposing inference of good faith, *see Tellabs*, 551 U.S. at 324, Plaintiffs have adequately plead scienter.

4. Loss Causation

Defendants further argue that Plaintiffs fail to allege with particularity how Biovie's alleged misrepresentations caused their economic losses. (ECF No. 38 at 29.) They contend that, although the revelation of data-integrity issues in November 2023 led to a stock price drop and investor losses, this revelation mattered to investors because "patient exclusions *on that larger scale* threatened (and then prevented) the study's statistical significance" but no facts suggest that the price drop occurred in reaction to alleged fraud at *fewer* sites. (*Id.* at 29-30.) Securities laws are not meant "to provide investors with broad insurance against market losses, but to protect them against those economic losses that misrepresentations actually cause". *Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 345. Under a "fraud-on-the market" theory of loss causation, unlike under a direct reliance theory, a plaintiff alleges that they "relied on the integrity of the market price [for shares] . . . which itself reflected all market data." *Atossa*, 868 F.3d at 795-96. "In a fraud-on-the market case . . . loss causation begins with the allegation that the defendant's misstatements . . . artificially inflated the price at which the plaintiff purchased [their] shares. Next, a plaintiff must allege that the truth

became known. Finally, a plaintiff must allege that the revelation caused the fraud-inducted inflation in the stock's price to be reduced or eliminated." *In re Genius Brands Intn'l Sec. Lit.*, 97 F.4th 1171, 1183 (9th Cir. 2024) (quoting *Dura Pharms.*, 544 U.S. at 347).

Plaintiffs adequately plead loss causation based on a fraud-on-the-market theory. Plaintiffs allege that Defendants made statements during the class period which artificially inflated the price of BioVie's stock, before the revelations in November 2023. Plaintiffs sustained economic losses after this information emerged. *See Yanek v. Staar Surgical Co.*, 388 F.Supp. 2d 1110, 1132 (C.D. Cal. 2005). Defendants' emphasis on the fact that the November disclosures revealed misconduct at many sites—and their argument that revealing issues at fewer sites would not have resulted in losses—is unavailing. *See Genius Brands*, 97 F.4th at 1183. Here, the stock losses in November 2023 are tied to compounded risks which BioVie allegedly failed to disclose earlier. *See, e.g.*, *Mineworkers' Pension Scheme v. First Solar, Inc.*, 881 F.3d 750, 753 (9th Cir. 2018) (internal citations omitted) (discussing allegations which suffice to "trace[] the loss back to the very facts about which the defendant lied"). Accordingly, the Court denies Defendants' Motion to the extent they request dismissal on loss causation grounds.

C. Scheme Liability & Section 20(a) Claim

Plaintiffs do not respond to Defendants' argument (ECF No. 38 at 30) on "scheme" liability under Rule 10b-5(a) or (c). The Court thus finds that Plaintiffs have conceded, by omission, any attempt to assert scheme liability under Section 10(b).

Finally, Plaintiffs assert in their response to BioVie's Motion that, by adequately pleading a primary violation, they have rebutted Defendants' only argument against secondary control-person liability claim under Section 20(a) (claim two) (ECF No. 38 at 32). (ECF No. 44 at 24.) Because Defendants do not move to dismiss Plaintiffs' Section 20(a) claim on any basis other than Plaintiffs' failure to plead a primary Section 10(b) violation, the Court will permit that claim to proceed.

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IV. CONCLUSION

The Court notes that the parties made several arguments and cited to several cases not discussed above. The Court has reviewed these arguments and cases and determines that they do not warrant discussion as they do not affect the outcome of the Motion before the Court.

It is therefore ordered that Defendants' motion to dismiss (ECF No. 38) is denied.

It is further ordered that Defendants' request for judicial notice (ECF No. 43) is granted in part and denied in part.

DATED THIS 27th Day of March 2025.

MIRANDA M. DU
CHIEF UNITED STATES DISTRICT JUDGE